



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 526, and 528

[Docket No. FDA-2015-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during March and April 2015. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect several nonsubstantive changes. These technical amendments are being made to improve the accuracy of the regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5689, [george.haibel@fda.hhs.gov](mailto:george.haibel@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during March and April 2015, as listed in table 1. In

addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading Room:

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm>. Marketing exclusivity and patent information may be accessed in FDA's

publication, Approved Animal Drug Products Online (Green Book) at:

<http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm>.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During March and April 2015

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Sections	FOIA Summary	NEPA Review
200-557	Putney, Inc., One Monument Sq., suite 400, Portland, ME 04101	Tiletamine-Zolazepam Injectable Solution (tiletamine HCl and zolazepam HCl)	Original approval as a generic copy of NADA 106-111	522.2470	yes	CE <sup>1,2</sup>
200-578	Belcher Pharmaceuticals, LLC, 6911 Bryan Dairy Rd., Largo, FL 33777	Carprofen Flavored Tablets (carprofen)	Original approval as a generic copy of NADA 141-053	520.304	yes	CE <sup>1,2</sup>
200-579	Ceva Santé Animale, 10 Avenue de la Ballastière, 33500 Libourne, France	Altrenogest Solution (altrenogest)	Original approval as a generic copy of NADA 141-222	520.48	yes	CE <sup>1,2</sup>
141-238	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	SPECTRAMAST LC (ceftiofur intramammary suspension) Sterile Suspension	Supplemental approval for treatment of diagnosed subclinical mastitis associated with coagulase-negative staphylococci and <u>Streptococcus dysgalactiae</u> in lactating dairy cattle.	526.313	yes	CE <sup>1,3</sup>
200-134	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	FERTAGYL (gonadorelin) Sterile Solution	Supplemental approval under section 512(b)(1) of the FD&C Act for use with cloprostenol injection to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows.	522.1077	yes	EA/ FONSI <sup>4</sup>

<sup>1</sup>The Agency has determined that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not have a significant effect on the human environment.

<sup>2</sup>CE granted under 21 CFR 25.33(a)(1).

<sup>3</sup>CE granted under 21 CFR 25.33(d)(5).

<sup>4</sup>The Agency has carefully considered an environmental assessment (EA) of the potential environmental impact of this action and has made a finding of no significant impact (FONSI).

In addition during March and April 2015, ownership of, and all rights and interest in, the following approved applications have been transferred as follows:

NADA/ ANADA	Previous Sponsor	New Animal Drug Product Name	New Sponsor	21 CFR Section
140-883	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee, Mission, KS 66201	LEGEND (hyaluronate sodium) Injectable Solution	Merial, Inc., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096	522.1145
141-188	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee, Mission, KS 66201	MARQUIS (ponazuril) Antiprotozoal Oral Paste	Merial, Inc., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096	520.1855
141-294	rEVO Biologics, 175 Crossing Blvd., Framingham, MA 01702	Bc6 rDNA construct in GTC 155-92 goats	LFB USA, Inc., 175 Crossing Blvd., Framingham, MA 01702	528.1070

At this time, the regulations are being amended to reflect these changes of sponsorship.

Following these changes of sponsorship, LFB USA, Inc., is now the sponsor of an approved application. Accordingly, § 510.600 (21 CFR 510.600) is being amended to add this firm to the list of sponsors of approved applications.

The animal drug regulations are also being amended to reflect several non-substantive changes. These technical amendments are being made to improve the accuracy of the regulations.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

#### 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 526, and 528

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, 526, and 528 are amended as follows:

**PART 510--NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. In § 510.600, in the table in paragraph (c)(1), remove the entry for "Abbott Laboratories" and add in alphabetical order an entry for "LFB USA, Inc."; and in the table in paragraph (c)(2), remove the entry for 000044 and add in numerical order an entry for "086047" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

Firm name and address	Drug labeler code
* * * * *	* *
LFB USA, Inc., 175 Crossing Blvd., Framingham, MA 01702	086047
* * * * *	* *

(2) \* \* \*

Drug labeler code	Firm name and address
* *	* * * * *
086047	LFB USA, Inc., 175 Crossing Blvd., Framingham, MA 01702
* *	* * * * *

## PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

4. In § 520.48, revise paragraph (b) to read as follows:

§ 520.48 Altrenogest.

\* \* \* \* \*

- (b) Sponsors. See Nos. 000061 and 013744 in § 510.600(c) of this chapter.

\* \* \* \* \*

§ 520.88g [Amended]

5. In § 520.88g, in paragraph (c)(2)(i), remove "(1 milliliter)".

6. In § 520.154a:

- a. Revise the section heading;

b. In paragraphs (d)(1)(ii), (d)(2)(i)(A), (d)(2)(ii)(A), and (d)(4)(ii), remove "bacitracin methylene disalicylate" and in its place add "bacitracin methylenedisalicylate"; and

c. In paragraph (d)(3)(ii), remove "Treponema hyodysenteriae" and in its place add "Brachyspira hyodysenteriae".

The revision reads as follows:

§ 520.154a Bacitracin methylenedisalicylate.

\* \* \* \* \*

§ 520.304 [Amended]

7. In § 520.304, in paragraph (b)(3), remove "No. 026637" and in its place add "Nos. 026637 and 062250".

§ 520.804 [Amended]

8. In § 520.804, redesignate paragraphs (c)(i), (c)(ii), and (c)(iii), as paragraphs (c)(1), (c)(2), and (c)(3).

9. In § 520.1660d, revise paragraph (a)(4) to read as follows:

§ 520.1660d Oxytetracycline powder.

(a) \* \* \*

(4) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 2.46 and 9.87 oz, 3.09 and 3.91 lb; pail: 3.09 lb).

\* \* \* \* \*

§ 520.1855 [Amended]

10. In § 520.1855, in paragraph (b), remove "000859" and in its place add "050604".

11. In § 520.2218, revise paragraphs (d)(1)(i)(A) and (B), and paragraphs (d)(2)(i)(A) and (B) to read as follows:

§ 520.2218 Sulfamerazine, sulfamethazine, and sulfaquinoxaline powder.

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(i) \* \* \*

(A) As an aid in the control of coccidiosis caused by Eimeria tenella and E. necatrix susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: Provide medicated water (0.04 percent solution) for 2 to 3 days, then plain water for 3 days, then medicated water (0.025 percent solution) for 2 days. If bloody droppings appear, repeat at 0.025 percent level for 2 more days. Do not change litter.

(B) As an aid in the control of acute fowl cholera caused by Pasteurella multocida susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: Provide medicated water (0.04 percent solution) for 2 to 3 days. If disease recurs, repeat treatment.

\* \* \* \* \*

(2) \* \* \*

(i) \* \* \*

(A) As an aid in the control of coccidiosis caused by Eimeria meleagritidis and E. adenoides susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: Provide medicated water (0.025 percent solution) for 2 days, then plain water for 3 days, then medicated water (0.025 percent solution) for 2 days, then plain water for 3 days, then medicated water (0.025 percent solution) for 2 days. Repeat if necessary. Do not change litter.

(B) As an aid in the control of acute fowl cholera caused by Pasteurella multocida susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: Provide medicated water (0.04 percent solution) for 2 to 3 days. If disease recurs, repeat treatment.

\* \* \* \* \*

§ 520.2640 [Amended]

12. In § 520.2640, in paragraphs (e)(2)(iii) and (e)(3)(iii), remove the first sentence.

#### PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

13. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§§ 522.1073 and 522.1075 [Removed]

14. Remove §§ 522.1073 and 522.1075.

15. Revise § 522.1077 to read as follows:



§ 522.1077 Gonadorelin.

(a) Specifications. Each milliliter (mL) of solution contains:

- (1) 43 micrograms (µg) of gonadorelin as gonadorelin acetate;
- (2) 100 µg of gonadorelin as gonadorelin acetate;
- (3) 50 µg of gonadorelin as gonadorelin diacetate tetrahydrate; or
- (4) 50 µg of gonadorelin as gonadorelin hydrochloride.

(b) Sponsors. See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 000061 for use of the 43-µg/mL product described in paragraph (a)(1) as in paragraphs (d)(1)(i), (d)(1)(iv), and (d)(2) of this section.

(2) No. 068504 for use of the 100-µg/mL product described in paragraph (a)(2) as in paragraphs (d)(1)(ii), (d)(1)(v), and (d)(2) of this section.

(3) Nos. 000859 and 050604 for use of the 50-µg/mL product described in paragraph (a)(3) as in paragraphs (d)(1)(ii) and (d)(2) of this section.

(4) No. 054771 for use of the 50-µg/mL product described in paragraph (a)(4) as in paragraphs (d)(1)(iii), (d)(1)(vi), and (d)(2) of this section.

(c) Special considerations. Concurrent luteolytic drug use is approved as follows:

(1) Cloprostenol injection for use as in paragraph (d)(1)(iv) of this section as provided by No. 000061 in § 510.600(c) of this chapter.

(2) Cloprostenol injection for use as in paragraph (d)(1)(v) of this section as provided by No. 000061 or No. 068504 in § 510.600(c) of this chapter.

(3) Dinoprost injection for use as in paragraph (d)(1)(vi) of this section as provided by No. 054771 in § 510.600(c) of this chapter.

(d) Conditions of use in cattle--(1) Indications for use and amounts--(i) For the treatment of ovarian follicular cysts in dairy cattle: Administer 86 µg gonadorelin by intramuscular or intravenous injection.

(ii) For the treatment of ovarian follicular cysts in dairy cattle: Administer 100 µg gonadorelin by intramuscular or intravenous injection.

(iii) For the treatment of ovarian follicular cysts in cattle: Administer 100 µg gonadorelin by intramuscular injection.

(iv) For use with cloprostenol injection to synchronize estrous cycles to allow for fixed-time artificial insemination (FTAI) in lactating dairy cows: Administer to each cow 86 µg gonadorelin by intramuscular injection, followed 6 to 8 days later by 500 µg cloprostenol by intramuscular injection, followed 30 to 72 hours later by 86 µg gonadorelin by intramuscular injection.

(v) For use with cloprostenol injection to synchronize estrous cycles to allow for fixed-time artificial insemination (FTAI) in lactating dairy cows and beef cows: Administer to each cow 100 µg gonadorelin by intramuscular injection, followed 6 to 8 days later by 500 µg cloprostenol by intramuscular injection, followed 30 to 72 hours later by 100 µg gonadorelin by intramuscular injection.

(vi) For use with dinoprost injection to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in lactating dairy cows: Administer to each cow 100 to 200 µg gonadorelin by intramuscular injection, followed 6 to 8 days later by 25 mg dinoprost by intramuscular injection, followed 30 to 72 hours later by 100 to 200 µg gonadorelin by intramuscular injection.

(2) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1145 [Amended]

16. In § 520.1145, in paragraph (e)(2)(i), remove "000859" and in its place add "050604".

17. In § 522.2470, revise paragraph (b) to read as follows:

§ 522.2470 Tiletamine and zolazepam for injection.

\* \* \* \* \*

(b) Sponsors. See Nos. 026637 and 054771 in § 510.600(c) of this chapter.

\* \* \* \* \*

18. In § 522.2483, revise paragraph (b) to read as follows:

§ 522.2483 Triamcinolone.

\* \* \* \* \*

(b) Sponsors. See Nos. 000010 and 054628 in § 510.600(c) of this chapter.

\* \* \* \* \*

## PART 526--INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

19. The authority citation for 21 CFR part 526 continues to read as follows:

Authority: 21 U.S.C. 360b.

20. In § 526.313, revise paragraph (d)(1)(ii) to read as follows:

§ 526.313 Ceftiofur.

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(ii) Indications for use. For use in lactating dairy cattle:

(A) For the treatment of clinical mastitis associated with coagulase-negative staphylococci, Streptococcus dysgalactiae, and Escherichia coli; and

(B) For the treatment of diagnosed subclinical mastitis associated with coagulase-negative staphylococci and S. dysgalactiae.

\* \* \* \* \*

#### PART 528--NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

21. The authority citation for 21 CFR part 528 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 528.1070 [Amended]

22. In § 528.1070, in paragraph (b), remove "042976" and in its place add "086047".

Dated: June 11, 2015.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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